

consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(b) *Classification*. Class I (general controls).

§ 866.3780 *Toxoplasma gondii* serological reagents.

(a) *Identification*. *Toxoplasma gondii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Toxoplasma gondii* in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Toxoplasma gondii* from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan *Toxoplasma gondii* and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

(b) *Classification*. Class II (performance standards).

§ 866.3820 *Treponema pallidum* nontreponemal test reagents.

(a) *Identification*. *Treponema pallidum* nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced

from the reaction of treponema microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus *Treponema* and provides epidemiological information on syphilis.

(b) *Classification*. Class II (performance standards).

§ 866.3830 *Treponema pallidum* treponemal test reagents.

(a) *Identification*. *Treponema pallidum* treponemal test reagents are devices that consist of the antigens, antisera and all control reagents (standardized reagents with which test results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA-ABS), the *Treponema pallidum* immobilization test (T.P.I.), and other treponemal tests used to identify antibodies to *Treponema pallidum* directly from infecting treponemal organisms in serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus *Treponema* and provides epidemiological information on syphilis.

(b) *Classification*. Class II (performance standards).

§ 866.3850 *Trichinella spiralis* serological reagents.

(a) *Identification*. *Trichinella spiralis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Trichinella spiralis* in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) *Classification*. Class I (general controls).

§ 866.3870 *Trypanosoma* spp. serological reagents.

(a) *Identification*. *Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies

to *Trypanosoma* spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma*. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) *Classification*. Class I (general controls).

§ 866.3900 Varicella-zoster virus serological reagents.

(a) *Identification*. Varicella-zoster virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to varicella-zoster in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

(b) *Classification*. Class II (performance standards).

§ 866.3930 *Vibrio cholerae* serological reagents.

(a) *Identification*. *Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated,

the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(b) *Classification*. Class II (performance standards).

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4100 Complement reagent.

(a) *Identification*. A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807.

§ 866.4500 Immunoelectrophoresis equipment.

(a) *Identification*. Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

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§ 866.4520 Immunofluorometer equipment.

(a) *Identification*. Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a